Roche’s Perjeta regimen extended the lives of people with an aggressive type of metastatic breast cancer by 15.7 months compared to Herceptin and chemotherapy

- Final data from Phase III CLEOPATRA study showed people with previously untreated HER2-positive metastatic breast cancer who received Perjeta, Herceptin and docetaxel chemotherapy lived a median of 56.5 months compared to 40.8 months for people who received Herceptin and chemotherapy1
- Median overall survival of almost five years is the longest observed to date in people with this aggressive type of advanced breast cancer1

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced final survival results from the Phase III CLEOPATRA study, which showed that adding Perjeta (pertuzumab) to Herceptin® (trastuzumab) and docetaxel chemotherapy extended the lives (overall survival; OS) of people with previously untreated HER2-positive metastatic breast cancer (mBC) by 15.7 months compared to Herceptin and chemotherapy (median OS: 56.5 vs. 40.8 months).1 No new safety signals were observed in the study.1 These data will be presented today in the Presidential Symposium at the European Society for Medical Oncology (ESMO) 2014 congress in Madrid, Spain (Abstract #350O_PR; Sunday, September 28, 4:00 – 5:30 p.m. CEST) and are also featured in the official ESMO Press Briefing.

"Adding Perjeta to treatment with Herceptin and chemotherapy resulted in the longest survival observed to date in a clinical study of people with HER2-positive metastatic breast cancer," said Sandra Horning, M.D., Roche’s Chief Medical Officer and Head, Global Product Development. "The median survival of nearly five years for people who received the Perjeta regimen is 15.7 months longer than for people who received Herceptin and chemotherapy alone, a magnitude of improvement we rarely see in clinical trials in advanced cancer.”
Perjeta in combination with Herceptin and docetaxel chemotherapy is approved in the United States and the EU for people with previously untreated HER2-positive mBC. The Perjeta regimen has also been granted accelerated approval as a neoadjuvant treatment (use before surgery) for HER2-positive early breast cancer (eBC) by the U.S. Food and Drug Administration (FDA). An application to update the Marketing Authorisation to include this indication has also recently been submitted to the European Medicines Agency.

About the CLEOPATRA Study

CLEOPATRA (CLinical Evaluation Of Pertuzumab And TRAstuzumab) was an international, Phase III, randomised, double-blind, placebo-controlled study. The study compared the combination of Perjeta, Herceptin and docetaxel chemotherapy with placebo, Herceptin and chemotherapy in 808 people with previously untreated HER2-positive mBC, or with HER2-positive mBC that had come back after prior therapy in the adjuvant or neoadjuvant setting. The primary endpoint of the study was progression-free survival (PFS) as assessed by an independent review committee. Secondary endpoints included OS and safety profile.

An interim OS analysis from the CLEOPATRA study was previously presented at the San Antonio Breast Cancer Symposium (SABCS) 2012. At the time of the analysis, median OS had not yet been reached for people receiving the Perjeta regimen as more than half of these people continued to survive. The results to be presented today are from the final pre-specified OS analysis after a median follow-up of 50 months; median OS has now been reached for people receiving the Perjeta regimen. These data will be submitted to the regulatory authorities around the world for inclusion in the prescribing information for Perjeta. The safety profile of Perjeta in this analysis was consistent with that observed previously in the CLEOPATRA study, including Perjeta’s long-term cardiac safety. No new safety signals were observed, and the OS results of this final analysis were consistent across patient subgroups.

Updates to previously reported OS, PFS and safety profile data from the CLEOPATRA study will also be presented today. These data showed:

- The risk of death was reduced by 32 percent for people who received the Perjeta regimen compared to those who received Herceptin and chemotherapy (HR=0.68, 95 percent CI 0.56-0.84; p=0.0002).
- People who received the Perjeta regimen had a 32 percent reduction in the risk of their disease worsening or death (PFS; HR=0.68, 95 percent CI 0.58-0.80) compared to people who received Herceptin and chemotherapy.
• With longer follow-up, the median PFS improvement of more than six months was maintained (median PFS of 18.7 months for people who received Perjeta, Herceptin and chemotherapy compared to 12.4 months for those who received Herceptin and chemotherapy).
• The most common adverse events (AEs, rate greater than 25 percent or greater than 5 percent difference between study groups) seen with the Perjeta regimen were diarrhoea, rash, mucosal inflammation, headache, upper respiratory tract infection, itching, low white blood cell count with fever, dry skin and muscle spasms.
• The most common Grade 3-4 AEs (rate greater than 10 percent) were low white blood cell count, low white blood cell count with fever and a decrease in a certain type of white blood cells.

About Perjeta
Perjeta is a medicine that targets the HER2 receptor, a protein found on the outside of many normal cells and in high quantities on the outside of cancer cells in HER2-positive cancers. Perjeta is designed specifically to prevent the HER2 receptor from pairing (or “dimerising”) with other HER receptors (EGFR/HER1, HER3 and HER4) on the surface of cells, a process that is believed to play a role in tumour growth and survival. Binding of Perjeta to HER2 may also signal the body’s immune system to destroy the cancer cells. The mechanisms of action of Perjeta and Herceptin are believed to complement each other, as both bind to the HER2 receptor, but to different places. The combination of Perjeta and Herceptin is thought to provide a more comprehensive blockade of HER signalling pathways.

About Roche’s medicines for HER2-positive breast cancer
Roche has been leading research into the HER2 pathway for over 30 years and is committed to improving the health, quality of life and survival for patients with both early and advanced HER2-positive disease.

Roche has developed three innovative medicines that have helped transform the treatment of HER2-positive breast cancer: Herceptin, Perjeta and Kadcyla. HER2-positive breast cancer is a particularly aggressive form of the disease that affects approximately 20 percent of patients. Over the past 15 years, the outlook for patients with HER2-positive disease has improved to the extent that patients with the disease treated with these innovative medicines now typically experience better outcomes than those patients with less aggressive HER2-negative disease.
Eligibility for treatment with Roche’s HER2-targeted medicines is determined via a diagnostic test, saving time from the outset by identifying those patients who will likely benefit from these medicines.

**About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013, the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit [www.roche.com](http://www.roche.com).

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**Additional information**

Roche in Oncology: [www.roche.com/media/media_backgrounder/media_oncology.htm](http://www.roche.com/media/media_backgrounder/media_oncology.htm)

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References
1. Swain S. et al. Final overall survival (OS) analysis from the CLEOPATRA study of first-line (1L) pertuzumab (Ptz), trastuzumab (T), and docetaxel (D) in patients (pts) with HER2-positive metastatic breast cancer (MBC). European Society for Medical Oncology 2014, abstract #350Q_PR